

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Komorowski, et al.
Appl. No.	:	11/136,794
Filed	:	May 24, 2005
For	:	CHROMIUM/BIOTIN TREATMENT OF DYSLIPIDEMIA AND DIET- INDUCED POST PRANDIAL HYPERGLYCEMIA
Examiner	:	Choi, Frank I.
Group Art Unit	:	1616

SECOND DECLARATION OF JAMES KOMOROWSKI UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, James Komorowski, declare and state as follows:

1. I am one of the named inventors on the above-captioned patent application, and am familiar with the contents of the patent application. I am the Vice President of Technical Services & Scientific Affairs at Nutrition 21, Inc., the assignee of the above-captioned patent application.

2. I have reviewed the above-captioned application in its entirety, including the specification, claims, and the Figures.

3. I designed and either performed or oversaw the experiments used to generate the data shown in Figures 13 and 14 of the above-captioned application. The actual values of the amounts of chromium and biotin used in the experiments depicted in Figures 13 and 14 are as follows: "Low Chromium" or "LC" treatments were 1 μ g Cr/kg. This translates to 60 μ g chromium per day for an average individual, assuming that the average individual is 60kg. "High Chromium" or "HC" refers to treatment of 10 μ g Cr/kg, *i.e.*, approximately 600 μ g chromium per day for an average individual. "Low Biotin" or "LB" refers to a treatment of 30 μ g biotin/kg, *i.e.*, approximately 1,800 μ g biotin per day for an average individual. "High Biotin" or "HB" refers to a treatment of 300 μ g biotin/kg, *i.e.*, approximately 18,000 μ g biotin per day for an average individual. Thus, Figures 13 and 14 show that the range of chromium and biotin that synergistically improve lipid profiles in the average individual is 60 μ g chromium to 600 μ g chromium and 1,800 μ g biotin to 18,00 μ g biotin. This range however, can be adjusted up or

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down to account for the variation in weight of individuals, *e.g.*, from about 25 μg chromium to about 2,000 μg chromium and from about 25 μg biotin to about 20 mg biotin per day.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: James Komorowski Date: March 13, 2007
James Komorowski

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